AMENDMENT UNDER 37 C.F.R. § 1.111

Application No.: 10/550,912

Attorney Docket No.: Q90112

**REMARKS** 

Claims 1- to 17 are all the claims pending in the present application.

Claim 9 has been objected to because of a typographical error.

In response, Applicants have amended claim 9 herein to correct the typographical error to

recite the correct term "(23:77)." Accordingly, Applicants request withdrawal of this objection.

Claims 1 - 12 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly

being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicant regards as the invention.

The Examiner sets forth three reasons for this rejection. Applicants discuss each of these

reasons below.

First, claim 1 was alleged to be vague because it was unclear to the Examiner whether the

cross-section of the aggregate of filaments is an irregular shape or whether the cross-section of

each of the filaments is an irregular shape.

In response, Applicants have amended claim 1 to replace the recitation "wherein any

given lateral cross-section of the filaments is an irregular shape" with the recitation "wherein any

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given lateral cross-section of each of the filaments is an irregular shape." Amended claim 1 is

supported in the specification, e.g., at page 6, lines 9 - 16.

With respect to claim 2, the manner in which "fine" is measured in comparison was

considered unclear.

In response, Applicants have amended claim 2 to replace the recitation "fine" with "0.1 -

1 μm." Amended claim 2 is supported, e.g., at page 6, lines 26 - 32.

Finally, with respect to claim 9, the reference to "based on weight" was considered

unclear.

With regard to claim 9, Applicants submit that the ratio is clearly based on the weights of

the solvents, since claim 9 itself clearly describes that the ratio of the volatile poor solvent and

volatile good solvent in the mixed solvent is in the range of (23:77) to (40:60), based on weight.

Similarly, the specification at page 8, lines 20 - 24 mentions that the volatile solvent may also be

a mixed solvent comprising a volatile good solvent and a volatile poor solvent, in which case the

ratio of the volatile poor solvent and volatile good solvent in the mixed solvent is preferably in

the range of (23:77) to (40:60), based on weight.

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In view of the above, Applicants submit that claims 1, 2 and 9 comply with the requirements of 35 U.S.C. § 112, second paragraph, and accordingly, request withdrawal of this rejection.

Claims 1 - 12 have been rejected under 35 U.S.C. § 102(e) or in the alterative, 35 U.S.C. § 103(a) as obvious over U.S. Patent Publication 2006/0057350 to Ochi et al.

Applicants submit that Ochi et al. do not disclose or render obvious the subject matter of claims 1 - 12 and, accordingly, request withdrawal of this rejection.

The present invention as set forth in claim 1 is directed to a nonwoven fabric characterized by being an aggregate of filaments composed of a thermoplastic polymer, and by having a mean fiber size of  $0.1 - 20 \mu m$ , wherein any given lateral cross-section of each of the filaments is an irregular shape, and a mean apparent density in the range of  $10 - 95 \text{ kg/m}^3$ .

In contrast, Ochi et al. do not provide a nonwoven fabric wherein any given lateral cross-section of the filament is an irregular shape, but instead, Ochi et al. provide a nonwoven fabric wherein any given lateral cross-section of the filament must be circular. This is because Ochi et al. apply, for example, islands-in-sea multi-component spinning technology for the production of microfibers. See page 8, paragraphs [0147] - [153] of Ochi et al. In that case, it is well known in the art that the island component has a tendency to minimize its surface area because of surface tension. Consequently, the microfibers are forced to have the simplest shape, so that the lateral cross-section of the filament is circular and the surface is smooth.

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Further, the Examiner has asserted that Ochi et al. inherently disclose the filaments of the present invention in paragraphs 0460, 0471, and 0484-0488, which according to the Examiner disclose electrospinning. The filaments of the present invention can be produced by an electrospinning method, as set forth in the specification. The paragraphs of Ochi et al. identified by the Examiner encompass Examples 48, 49, and 53, where Ochi et al. teach producing microfibers using islands-in-sea multi-component spinning technology. Examples 48, 49, and 53, which are based on Example 1 of Ochi et al., do not disclose a process of electrospinning a thermoplastic with a solvent.

Accordingly, Ochi et al. do not teach a similar structural and chemical composition as the claimed invention made by a substantially similar process, and thus, claims 1 - 12 are not inherently anticipated by Ochi et al.

Further, Applicants submit that Ochi et al. teach away from applying an electrospinning method for preparing microfibers. See paragraphs 0009, 0126, 0139, and 0203, where Ochi et al. set forth a variety of reasons teaching away from electrospinning.

In view of the above, Applicants submit that claims 1 - 12 of the present application are novel and not obvious over Ochi et al. Accordingly, Applicants request the Examiner to withdraw the rejection under 35 U.S.C. § 102(e), or in the alternative 35 U.S.C. § 103(a), based on Ochi et al.

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Claims 1 - 12 have been rejected under 35 U.S.C. § 103(a) as obvious over U.S. Pub. No.

2002/0192449 to Hobbs et al. in view of U.S. Patent 4,701,267 to Watanabe et al.

As discussed above, the present invention provides a nonwoven fabric that is an

aggregate of filaments composed of a thermoplastic polymer, and having a mean fiber size of 0.1

- 5 μm, wherein any given lateral cross-section of each of the filaments is an irregular shape, and

having a mean apparent density in the range of 10 - 95 kg/m<sup>3</sup>.

The nonwoven fabric of the present invention has a surface area sufficiently large as a

matrix for cell culturing in the field of regenerative medicine, with large gaps between filaments

and a low apparent density suitable for cell culturing. The above features of an irregular shape

and a mean apparent density in the range of 10 - 95 kg/m<sup>3</sup> are indispensable, and these

requirements must be met simultaneously for the purpose of the present invention, including

application for scaffold for cell culturing.

The Examiner has asserted that Hobbs et al. disclose a nonwoven fabric that is an

aggregate of filaments composed of a thermoplastic polymer, and having a mean fiber size of .1 -

20 μm, wherein any given lateral cross-section of the filaments is an irregular shape.

The Examiner has asserted that Watanabe et al. indicate conventional specifications as to

mean apparent density for the present purpose, and that Watanabe et al. provide this conventional

teaching showing that it is known in the medical industry fabric art to form a nonwoven fabric

comprising thermoplastic microfibers wherein the density of the fabric is from 0.01 g/cm<sup>3</sup> - 0.7

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g/cm<sup>3</sup>. The Examiner asserts that one of ordinary skill would have combined the teachings of Watanabe et al. with those of Hobbs et al., motivated by the expectation of forming a conventional medical industry fabric according to specifications known in the art which are suitable for the desired application as a wound dressing or filter.

The Examiner apparently understands the present invention as just a "medical industry fabric," such as fabric for filtration. However, the nonwoven fabric of the present invention can also be used as cell growth matrices (scaffold) in the field of regenerative medicine. Therefore, additional requirements must be met for the purpose.

Further, although Watanabe et al. broadly disclose a nonwoven fabric having a bulk density of 0.01 - 0.7 g/cm<sup>3</sup>, Watanabe et al. do not disclose a general method for manufacturing a nonwoven fabric having an ultra low bulk density within 10 - 95 kg/m<sup>3</sup>. Accordingly, a person of ordinary skill in the art would not have been able to produce the desired nonwoven fabric having an ultra low bulk density of 10 - 95 kg/m<sup>3</sup>, wherein any given lateral cross-section of the filaments is an irregular shape. Thus, Applicants submit that Watanabe et al. does not provide an enabling disclosure of the desired nonwoven fabric having a bulk density of 10 - 95 kg/m<sup>3</sup>, wherein any given lateral cross-section of the filaments is an irregular shape.

Applicants point out that the lowest actual bulk density disclosed in Watanabe et al. appears in Example 1, where Watanabe et al. disclose a bulk density of 0.18 g/cm<sup>3</sup>, corresponding to 180 kg/m<sup>3</sup>, which is higher than the upper value of 95 kg/m<sup>3</sup> and outside the

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range of the present claims. Watanabe et al. nowhere suggest the bulk density range set forth in

the present claims.

The inventors of the present invention solved the problem by applying a specific

production method that comprises a step wherein a thermoplastic polymer is dissolved in a

mixed solvent composed of a volatile good solvent and a volatile poor solvent, a step wherein the

resulting solution is spun by an electrospinning method, and a step wherein a nonwoven fabric

accumulated on a collecting sheet is obtained. Neither Hobbs et al. nor Watanabe et al. disclose

or suggest such a method.

Further, according to the examples in the present application, the mean apparent density

of the nonwoven fabric has a particular numerical value depending on each manufacturing

condition, such as the sort of solvents used, and the ratio of a volatile good solvent to a volatile

poor solvent. This indicates that the mean apparent density was not a feature that can be

controlled arbitrarily before the present invention.

In view of the above, Applicants submit that claim 1 of the present application and the

claims dependent thereon are not obvious from the disclosures of Hobbs et al. and Watanabe et

al.

Accordingly, Applicants request withdrawal of the rejection under 35 U.S.C. § 103(a)

based on Hobbs et al. in view of Watanabe et al.

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In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby earnestly solicited.

If any points remain in issue which the Examiner feels may be best resolved through a

personal or telephone interview, the Examiner is kindly requested to contact the undersigned

attorney at the local Washington, D.C. telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

SUGHRUE MION, PLLC

Telephone: (202) 293-7060

Facsimile: (202) 293-7860

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CUSTOMER NUMBER

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